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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,754	04/11/2007	Xian-Ming Zeng	TEVE-113US	3414

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EXAMINER	
YU, HONG	

ART UNIT	PAPER NUMBER
1616	

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12/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,754	ZENG ET AL.	
	Examiner	Art Unit	
	HONG YU	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *18 and 20-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/17/2009 and 09/21/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-46 are pending. This application is a national stage entry of PCT/US04/30724, filled on 09/18/2004. This application claims foreign priority to GB 0321873.2, filed on 09/18/2003 in great Britain and to GB 0403262.9, filed on 02/13/2004 in Great Britain.

Election/Restrictions

Applicant's election with traverse of group I, claims 1-19, and species election of shape of particle in claim 5 and election without traverse of active ingredient in claim 17 in the reply filed on 09/04/2009, is acknowledge.

The traversal is on the ground(s) that US 6,290,991 does not disclose the special technical feature of groups I-III. This is not found persuasive because, as stated in the restriction requirement mailed on 08/04/2009, the special technical feature of groups I-III is non-crystalline particles for inhalation delivery. The element cannot be a *special technical feature* under PCT Rule 13.2 because the element is shown in prior art. US 6,290,991 B1 (cited in international search report) teaches a therapeutic composition comprising non-crystalline particles for inhalation (claim 1). Consequently, groups I-III are not linked by the same or a corresponding special feature as to form a single general inventive concept.

Restriction for examination purposes as indicated is proper because all these inventions are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required and the

inventions require different search queries as well are likely to raise different non-prior are issues under 35 USC 112, first paragraph.

The argument of applicants about the species election for particle shape is noted and considered convincing by the examiner. Thus, the species election requirement for particle shape is withdrawn by the examiner.

The restriction requirement and species election of active agents are still deemed proper and are therefore made FINAL.

Claims 18 and 20-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim.

Claims 1-17 and 19 will presently be examined to the extent they read on the elected subject matter of record.

Claim Objections

Claims 9, 12-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only--, and/or, --cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Claims 10, 11, 17, and 19 are objected as being dependent claim of an improper multiple dependent claims.

Claim Rejections - 35 USC § 112/Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "substantially" renders the claim indefinite. The term “substantially” is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what is encompassed and excluded by the limitation "substantially”. One of ordinary skill could not ascertain and interpret the metes and bounds of the patent protection desired as to these terms. Thus, it is unclear and indefinite as to how the “substantially”, herein is encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Redkar et al. (US 6,482,830 B1).

Redkar et al. meet all of the limitations of the claims 1 and 2. Redkar et al. disclose a pharmaceutical composition for inhalation comprising an amorphous active agent and a pharmaceutical carrier (column 4, line 58-63 and claim 12).

Claims 1-16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolfe et al. (US 2002/0081266 A1).

Woolfe et al. meet all of the limitations of the claims 1-8, 12-15, and 19. Woolfe et al. disclose a nasal inhaler composition comprising a mixture of particles of two or more amorphous drugs and an excipient (such as mannitol) produced by spray drying with smooth surface and are elliptical, oval or spherical (paragraph 15, 20, 36, 89, claim 15, and claim 18). Woolfe et al. disclose particles of the same active agents produced with the same spray drying method as that of the particles recited in the instant claims, the particles disclosed by Woolfe et al. necessarily have the shape of oblate spheroidal. The excipient disclosed by Woolfe et al. is as same as the excipient recited in the instant disclosure of the specification (paragraph 23), thus the excipient disclosed by Woolfe et al. is necessarily soluble in condition obtaining in the nose, lung, or mouth of a human or animal. It is disclosed in the instant disclosure of the specification that the particles produced with spray drying method are electrically uncharged, thus the particles produced with spray drying method disclosed by Woolfe et al. are necessarily electrically uncharged.

Woolfe et al. meet all of the limitations of the claims 9-11. Woolfe et al. disclose particles of active agent with particle size of less than ~3 μm and over 50% of the particles with a dimension between 1 and 5 μm (paragraph 39 and 90).

Woolfe et al. meet all of the limitations of the claim 16. Woolfe et al. disclose a nasal inhalation composition comprising a short, medium, or long acting β agonist and a steroid (claim 10-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolfe et al. (US 2002/0081266 A1) in view of Keller et al. (US 6,475,467 B1).

Applicant's claims

The instant claims 1, 15, and 17 recite inhalation composition comprising at least one non-crystalline active agent which are fluticasone dipropionate and salmeterol xinafoate.

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

The teachings of Woolfe et al. are discussed above and applied in the same manner.

Ascertainment of the Difference between Scope of the Prior Art and the Claims

MPEP 2141.02)

Woolfe et al. do not specify the active agents are fluticasone dipropionate and salmeterol xinafoate, but specify the active agents are fluticasone and salmeterol (claims 10, 11, and 14).

This deficiency is cured by Keller et al. who teach an inhalation composition comprising fluticasone dipropionate as fluticasone and salmeterol xinafoate as salmeterol (column 5, line 21-36 and claim 10).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP 2142-2143)

Woolfe et al. specify the active agents are fluticasone and salmeterol; Keller et al. teach an inhalation composition comprising fluticasone dipropionate as fluticasone and salmeterol xinafoate as salmeterol. It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Woolfe et al. and Keller et al. to specify fluticasone dipropionate as fluticasone and salmeterol xinafoate as salmeterol. Fluticasone dipropionate is a well known fluticasone and salmeterol xinafoate is a well known salmeterol to a person of ordinary skill in the art at the time of the invention. It is generally considered to be prima facie obvious to specify components which are taught by the prior art to be well known and useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for specifying them flows from their having been used in the prior art, and from their being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the specifying a conventional β agonist and a conventional steroid. It therefore follows that the instant claims define prima facie obvious subject matter.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328. The examiner can normally be reached on M-Th 8:50 am-6:50 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Y./
Examiner, Art Unit 1616

HY

/Mina Haghighatian/
Primary Examiner, Art Unit 1616